JAN 1 2 2001

# 510(K) SUMMARY

K003223

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: **Geon Corp.**
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   Phone: 001-886-4-8852476
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   Contact: Mr. Henry Chen, General Manager

2. Device Name
   Trade Name: GEON Digital Clinical Thermometer
   Common Name: Oral / Armpit Thermometer
   Classification name: Clinical Electronic Thermometer

3. Classification: Class II

4. Predicate Device: VALEO Clinical Electronic Thermometer ( K982140 )
   DUTECK Industrial Co. Ltd. (K992327)

5. Device Description: The Geon Digital Clinical Thermometer, is an electronic thermometer using to detect body temperature for Armpit or Oral use.

6. Intended Use: The Geon Digital Clinical Thermometer is used to measure human body temperature with the following features:
   * The device display body temperature in digital format at LCD.
   * The device make intended contact with patient in 2 ways
     (1) Surface contact: Armpit
     (2) Invasive contact: Oral

   The device is to used and installed by Patient, Nurse, Doctor & persons with the exception of Handicapped persons and Children.
   The device is to used in the ENVIRONMENT of room temperature & normal environment condition.

7. Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included ASTM E1112, EN 60601-1 and EN 60601-1-2 requirements.

8. Conclusions:

The GEON Digital Clinical Thermometer have the same intended use and similar technological characteristics as the VALEO Clinical Electronic Thermometer ( K982140 ). Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the GEON Digital Clinical Thermometer is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2001

C/O Mr. Allen Reich
Geon Corporation
900 North Switzer Canyon Drive, Suite 142
Flaggstaff, Arizona 86001

Re: K003223
Trade Name: Geon Digital Clinical Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 16, 2000
Received: October 16, 2000

Dear Mr. Reich:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Premarket Notification

# INDICATIONS FOR USE STATEMENT



510 (k) NUMBER (IF KNOWN): K003223 wmb ~~K003223~~

DEVICE NAME: **GEON Digital Clinical Thermometer**
GEON CORP..

INDICATIONS FOR USE:

The **GEON Digital Clinical Thermometer** is a non-sterile, reusable Clinical Thermometer intended for determination of Axially ,Oral & Rectal human body temperature with the following features:

* The device display body temperature in digital format at LCD.
* The device make intended contact with patient in 3 ways
  (1) Surface contact: Armpit
  (2) Invasive contact: Oral & Rectal

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Catherine Cesarette
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003223

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The-counter ✓
(Per 21 CFR 801.109) (Optional Format)